

REMARKS

Claims 1-10 are pending in this application. By this Amendment, claims 1 and 7 are amended. Support for the amendments to claims 1 and 7 can be found in the specification as originally filed, for example, at page 6, line 27 - page 7, line 33; and in originally filed claims 1 and 7. No new matter is added by these amendments.

Entry of the amendments is proper under 37 CFR §1.116 since the amendments: (a) place the application in condition for allowance for the reasons discussed herein; (b) do not raise any new issue requiring further search and/or consideration as the amendments amplify issues previously discussed throughout prosecution; (c) satisfy a requirement of form asserted in the previous Office Action; (d) do not present any additional claims; and (e) place the application in better form for appeal, should an appeal be necessary. The amendments are necessary and were not earlier presented because they are made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

I. Objections to the Specification

The Office Action objects to the specification as unclear and asserts that the term "minimal medium" in Table 2 and on page 16 is unclear. In particular, the Office Action asserts that it is not clear whether yeast extract is required for fermentation and that the disclosed minimal medium does not comprise yeast extract. Applicant respectfully disagrees.

The term "minimal medium" is defined in the specification at page 8, line 20 - page 9, line 2. Specifically, preparation of minimal media for the growth of *Bacillus smithii* is described, and the components of the minimal medium are indicated. See Specification, page 8, line 20 - page 9, line 2. Each liter of minimal medium includes inorganic salts in specified amounts, 2 g DAP, 3.5 g DAS, 0.5 g KCl and 15 mg MgCl₂; a buffer, 10 g BIS-TRIS; and trace elements. See Specification, page 8, lines 20-22; page 8, line 29 - page 9, line 2. Minimal medium also includes 3% pentose carbon sources. See Specification, page 8,

lines 24-26. In addition, minimal medium includes growth factors, 0.024 mg/l biotine, 0.012 mg/l thiamine, 0.02 g/l methionine, and 0.05 g/l yeast extract. *See* Specification, page 8, lines 27-29. That is, the minimal medium for *Bacillus smithii* growth is defined as including yeast extract.

Applicant respectfully submits that Table 2 is not unclear, because its recitation of minimal medium corresponds to the minimal medium defined at page 8, line 20 - page 9, line 2, which includes yeast extract. This is consistent with the example described in the specification at page 16, in which additional yeast extract is added to the minimal medium during fermentation, due to low biomass concentration. *See* Specification, page 16, lines 1-13. Thus, the term "minimal medium" and the specification are not unclear.

Accordingly, Applicant respectfully requests withdrawal of the objection to the specification.

II. Claim Rejections Under 35 U.S.C. §112

The Office Action rejects claims 7, 9 and 10 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Applicant respectfully traverses the rejection.

The Office Action asserts that claim 7, from which claims 9 and 10 depend, is confusing because no broth is recited in claim 1, from which claim 7 depends. Applicant respectfully submits that claim 1 has been amended herein to set forth a fermentation broth. Applicant respectfully submits that the fermentation broth of claim 7 clearly refers to the fermentation broth of claim 1, and that claim 7 and its dependent claims are not indefinite.

In addition, the Office Action asserts that claims 9 and 10 are confusing because it is unclear whether the "wherein" clause of these claims modifies the purification steps (claims 9 and 10, respectively), the separation step (claim 7) or some undefined step. Applicant respectfully disagrees with this assertion.

The wherein clause of claims 9 and 10 sets forth that "the moderately thermophilic *Bacillus* species is grown on a chemically defined medium." One of ordinary skill in the art would understand from this clause that the moderately thermophilic *Bacillus* species of independent claim 1 is grown on a chemically defined medium prior to the fermentation of claim 1. *See e.g.*, Specification, page 6, line 37 - page 7, line 6. That is, one of ordinary skill would understand claim 9, for example, to set forth a process in which moderately thermophilic *Bacillus* species that were grown on a chemically defined medium are used to homolactically and anaerobically ferment pentose-containing substrates to form lactic acid and/or lactate, biomass is removed from the fermentation broth, and thereafter the lactic acid and/or lactate are separated from the fermentation broth. Because the wherein clause of claims 9 and 10 would be understood by one of skill in the art as modifying the moderately thermophilic *Bacillus* species of independent claim 1, and not any of the process steps, Applicant respectfully submits that claims 9 and 10 are not indefinite.

Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

III. Claim Rejections Under 35 U.S.C. §102

The Office Action rejects claims 1-5 and 7 under 35 U.S.C. §102(b) over Payot et al., "Lactic Acid Production by *Bacillus Coagulans* - Kinetic Studies and Optimization of Culture Medium for Batch and Continuous Fermentations," ENZYME AND MICROBIAL TECHNOLOGY, Vol. 24, 1999, pp.191-199, in light of Godshall et al., "Effect of Macromolecules on Sugar Processing: Comparison of Cane and Beet Macromolecules," AVH ASSOCIATION, 9th Symposium, pp. 23-30. Applicant respectfully traverses this rejection.

The Office Action takes the position that Payot teaches all of the features of claim 1 and dependent claims 2-5 and 7, because Payot teaches producing lactic acid from molasses by *Bacillus coagulans* fermentation. The Office Action asserts that Godshall discloses, in

Tables 3 and 4, that molasses comprises glucose, xylose and arabinose. Applicant respectfully disagrees.

Independent claim 1 sets forth a "[p]rocess for preparation of lactic acid and/or lactate, comprising: homolactically and anaerobically fermenting in a fermentation broth a pentose-containing substrate by a moderately thermophilic *Bacillus* species to form lactic acid and/or lactate." Claims 2-5 and 7 depend from claim 1 and incorporate all of the limitations thereof.

Claim 1 sets forth a process comprising a single step, a fermenting step. The "comprising" language of the claim indicates that any process including the claimed fermenting step, with or without other steps, is within the scope of the claim. However, the fermenting step of claim 1 itself is more specific, requiring (a) homolactic and anaerobic conditions, (b) a substrate containing pentoses, and (c) a moderately thermophilic *Bacillus* species.

Specifically, claim 1 requires a pentose-containing substrate. By definition, pentoses are monomers, or monosaccharides. Specifically, a pentose is a "carbohydrate with 5 carbon atoms" or a "monosaccharide containing five carbon atoms in a molecule." See MSN Encarta Dictionary, pentose, at http://Encarta.msn.com/dictionary_/pentose.html; National Institutes of Health Online Thesarus, pentose, at <http://crisp.cit.nih.gov/Thesarus/00006117.htm>; see also Online Dictionary, pentose, <http://onlinedictionary.datasegment.com/word/pentose> (attached). When pentoses are polymerized to polysaccharides, they are no longer called pentoses, but rather pentosans. A pentosan is defined and understood in the art to be an "organic compound found in plants, whose polysaccharide carbohydrates break down to form pentoses" or an "anhydride or polymerized form of any pentose." See MSN Encarta Dictionary, pentosan, at http://Encarta.msn.com/dictionary_1861724833/pentosan.html; National Institutes of Health Online Thesarus, pentosan, at <http://crisp.cit.nih.gov/Thesarus/00006116.htm>; see also Online Dictionary, pentosan,

<http://onlinedictionary.datasegment.com/word/pentosan> (attached). Neither Payot nor Godshall teach pentose-containing substrates, as required by the fermentation step of claim 1.

Payot discloses the fermentation of molasses by *Bacillus coagulans* to form lactic acid. *See generally* Payot. However, contrary to the indication in the Office Action, molasses does not include pentoses, such as xylose or arabinose. The typical composition of cane molasses, according to United States Sugar Corporation, includes fructose and glucose, which are both hexoses, and sucrose, a disaccharide formed from fructose and glucose, but does not include any pentoses. *See* Molasses Composition (provided with March 8, 2005 Amendment).

The Office Action discounts the Molasses Composition document, asserting that there is no evidence that this reference provides the complete composition, but that it only gives components of interest to the United States Sugar Corporation. However, the first page of the Molasses Composition document indicates that the molasses composition as given is a typical composition of cane molasses, not merely a partial composition. *Id.* The amounts of molasses constituents are disclosed to the ppm level, and compounds sought but not detected are disclosed as "negligible." *Id.* However, no pentoses are disclosed as present, even in negligible amounts. *See generally* Molasses Composition. Under these circumstances, it is unlikely that pentoses would be present in any amounts but not mentioned. Thus, it is reasonable to infer that molasses does not contain pentose monosaccharides.

Godshall does not support the Office Action assertion that molasses is a pentose-containing substance. Rather, Godshall compares and discloses the compositions of macromolecules of cane and beet sugars, specifically polysaccharides. *See* Godshall, page 26, col. 2, line 5 - page 28, line 26; Tables 3-7. The macromolecules or polysaccharides of cane and beet sugars are made of units including arabinose, xylose and glucose, which are disclosed only as parts of polysaccharides. *Id.* That is, Godshall only discusses these

monomer units as parts of the polysaccharides in cane and beet sugars, not as individual monosaccharides. *Id.* In contrast, claim 1 requires a pentose-containing substrate, that is a substrate that contains pentose monomers, not polymerized pentoses. Thus, Godshall teaches substrates containing polysaccharides, but does not teach substrates containing pentose monosaccharides, as required by claim 1. Thus, Godshall does not provide support for the position that Payot's disclosure of molasses fermentation teaches fermentation of pentose-containing substrates.

Because molasses is not a pentose-containing substrate, as set forth in claim 1, Applicant respectfully submits that claims 1-5 and 7 are patentable over Payot, in light of Godshall, at least because Payot does not disclose fermenting by *Bacillus coagulans* of a pentose-containing substance.

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection.

IV. Claim Rejections Under 35 U.S.C. §103

A. Claims 1-5 and 7-9

The Office Action rejects claims 1-5 and 7-9 under 35 U.S.C. §103(a) over PCT International Publication No. WO 03/008601 A2 to Green et al. in view of Payot et al., "Lactic Acid Production by *Bacillus Coagulans* - Kinetic Studies and Optimization of Culture Medium for Batch and Continuous Fermentations," ENZYME AND MICROBIAL TECHNOLOGY, Vol. 24, 1999, pp.191-199 and in light of Godshall et al., "Effect of Macromolecules on Sugar Processing: Comparison of Cane and Beet Macromolecules," AVH ASSOCIATION, 9th Symposium, pp. 23-30. Applicant respectfully traverses this rejection.

Claim 1 is as set forth above. Claims 2-5 and 7-9 depend, directly or indirectly, from claim 1 and incorporate all of the limitations thereof.

The Office Action cites Green as teaching a process for homolactically fermenting a pentose-containing substance using moderately thermophilic *Bacillus* species, as set forth in claim 1, and teaches the subject matter of the dependent claims. While the Office Action admits that Green does not teach anaerobic fermentation or separation of the biomass or product, it relies on Payot for its teachings on these subjects. Thus, the Office Action takes the position that the subject matter of claims 1-5 and 7-9 would have been obvious over Green, in view of Payot. Applicant respectfully disagrees.

Applicant respectfully submits that Green is not available as prior art to the above-captioned application. The Green PCT application, PCT/GB02/03272, was first published as International Publication No. WO 03/008601 on January 30, 2003. Although the PCT application claims priority to British Patent Application No. 01175512, filed July 18, 2001, neither the PCT application or its priority application were published until January 30, 2003. However, the instant application was filed January 13, 2004, and claims priority to U.S. Provisional Application No. 60/439,469. The provisional application was filed on January 13, 2003, before the first publication of Green. Because Green was not published until after the first U.S. filing date of the instant application, Green is not available as prior art under §102 or §103.

Thus, regardless of its actual disclosures, Green cannot support a rejection of the pending claims. Payot and Godshall also cannot support a rejection of claims 1-5 and 7-9.

As discussed above, Payot discloses the fermentation of molasses by *Bacillus coagulans* to form lactic acid, but neither Payot nor Godshall discloses or suggests the fermentation of pentose-containing substrates. *See generally* Payot; Godshall. In addition, Payot also does not teach anaerobic fermentation; rather, Payot teaches that biomass is increased with aeration. *See* Payot, page 196, col. 1, lines 13-16.

Because neither Payot nor Godshall discloses or suggests at least these features of claim 1, claim 1 and its dependent claims would not have been obvious over Payot and Godshall, individually and in combination.

Applicant respectfully submits that claims 1-5 and 7-9 are patentable over Green in view of Payot and Godshall, at least because Green is not available as prior art to the claims and because neither secondary reference, Payot and Godshall, discloses or suggests anaerobic fermentation by *Bacillus* species. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. Claim 6

The Office Action rejects claim 6 under 35 U.S.C. §103(a) over PCT International Patent Application Publication No. WO 03/008601 A2 to Green et al. in view of Payot et al., "Lactic Acid Production by *Bacillus Coagulans* - Kinetic Studies and Optimization of Culture Medium for Batch and Continuous Fermentations," ENZYME AND MICROBIAL TECHNOLOGY, Vol. 24, 1999, pp.191-199, in view of Godshall et al., "Effect of Macromolecules on Sugar Processing: Comparison of Cane and Beet Macromolecules," AVH ASSOCIATION, 9th Symposium, pp. 23-30, as applied to claims 1-5 and 7-9, and further in view of U.S. Patent No. 4,110,477 to Naruse et al. Applicant respectfully traverses this rejection.

Claim 6 depends from claim 1, which is as set forth above, and further sets forth that the "fermenting is performed by a mixture of moderately thermophilic *Bacillus* species and another lactic-acid producing microorganism." Claim 6 incorporates all of the limitations of claim 1.

The Office Action applies Green and Payot in the same manner as to claims 1-5 and 7-9, discussed above, and admits that Green and Payot do not disclose or suggest that a mixture of bacteria may be used for fermentation. The Office Action relies on Naruse for its disclosures of fermentation by bacteria mixtures. Thus, the Office Action takes the position

that Green, Payot and Naruse, in combination, would have rendered the subject matter of claim 6 obvious. Applicant respectfully disagrees.

As discussed above, Green is not available as prior art under either §102 or §103, and neither Payot nor Godshall discloses or suggests anaerobic fermentation of pentose-containing substrate. Naruse does not remedy this shortcoming of Payot and Godshall.

Although Naruse does teach mixtures of *Bacillus natto* and lactic acid bacteria for fermentation, Naruse does not teach or suggest either anaerobic fermentation or pentose-containing substrates. *See generally* Naruse. Thus, Naruse, like Payot and Godshall, does not disclose or suggest anaerobic fermentation of pentose-containing substrates. For at least this reason, Naruse cannot overcome the deficiencies of the combination of Payot and Godshall. Any combination of the Payot, Godshall and Naruse references would still not provide a process that comprises fermentation of a pentose-containing substrate, as claimed.

Applicant respectfully submits that claim 6 is patentable over Green in view of Payot, in view of Godshall, and Naruse, at least because Green is not available as prior art to the claims and because none of Payot, Godshall and Naruse discloses or suggests anaerobic fermentation by *Bacillus* species. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

C. Claim 10

The Office Action rejects claim 10 under 35 U.S.C. §103(a) over PCT International Patent Application Publication No. WO 03/008601 A2 to Green et al. in view of Payot et al., "Lactic Acid Production by *Bacillus Coagulans* - Kinetic Studies and Optimization of Culture Medium for Batch and Continuous Fermentations," ENZYME AND MICROBIAL TECHNOLOGY, Vol. 24, 1999, pp.191-199, in view of Godshall et al., "Effect of Macromolecules on Sugar Processing: Comparison of Cane and Beet Macromolecules," AVH ASSOCIATION,

9th Symposium, pp. 23-30, as applied to claims 1-5 and 7-9, and further in view of U.S. Patent No. 5,002,881 to Van Nispen et al. Applicant respectfully traverses this rejection.

Claim 10 depends from claim 7, which in turn depends from claim 1, which is set forth above, and further sets forth that the "subjecting the lactic acid and/or lactate to one or more purification steps after separating the lactic acid and/or lactate from the fermentation broth, wherein the moderately thermophilic *Bacillus* species is grown on a chemically defined medium," with claim 7 introducing the separation of lactic acid and/or lactate from the fermentation broth. Claim 10 incorporates all of the limitations of claims 1 and 7.

The Office Action applies Green and Payot in the same manner as to claims 1-5 and 7-9, discussed above, and admits that Green and Payot do not disclose or suggest purification steps, as set forth in claim 10. The Office Action relies on Van Nispen for its disclosures of processes for fermenting organic acids in which bacteria are separated from the culture medium and impurities are removed. Thus, the Office Action takes the position that Green, Payot and Van Nispen, in combination, would have rendered the subject matter of claim 10 obvious. Applicant respectfully disagrees.

As discussed above, Green is not available as prior art under either §102 or §103, and neither Payot nor Godshall discloses or suggests anaerobic fermentation of pentose-containing substrate. Van Nispen does not remedy this shortcoming of Payot and Godshall.

Although Van Nispen does teach mixtures of *B. coagulans* and lactic acid bacteria for fermentation, Van Nispen does not teach or suggest either anaerobic fermentation or pentose-containing substrates. *See generally* Van Nispen. Thus, Van Nispen, like Payot and Godshall, does not disclose or suggest anaerobic fermentation of pentose-containing substrates. For at least this reason, Van Nispen cannot overcome the deficiencies of the combination of Payot and Godshall. Any combination of the Payot, Godshall and Van

Nispen references would still not provide a process that comprises fermentation of a pentose-containing substrate, as claimed.

Applicant respectfully submits that claim 10 is patentable over Green in view of Payot, in view of Godshall, and Van Nispen, at least because Green is not available as prior art to the claims and because none of Payot, Godshall and Van Nispen discloses or suggests anaerobic fermentation by *Bacillus* species. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

V. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1-10 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



William P. Berridge
Registration No. 30,024

Julie M. Seaman
Registration No. 51,156

WPB:JMS/jms

Attachments:

MSN Encarta Dictionary, pentose, at http://Encarta.msn.com/dictionary_/pentose.html
National Institutes of Health Online Thesaurus, pentose, at
<http://crisp.cit.nih.gov/Thesaurus/00006117.htm>
Online Dictionary, pentose, <http://onlinedictionary.datasegment.com/word/pentose>
MSN Encarta Dictionary, pentosan, at
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[pentyl acetate](#)
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pen·tose [pén tōss] (*plural* pen·toses)

noun

carbohydrate with 5 carbon atoms: a carbohydrate found in plants and nucleic acids that is a monosaccharide whose molecules each contain five carbon atoms

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pentosan

pen·to·san [péntə sən]

noun

plant polysaccharide: an organic compound found mainly in plants, whose polysaccharide carbohydrates break down to form pentoses

↑

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penthouse
pentimento
Pentland Firth
pentlandite
pentobarbital sodium
pentobarbitone sodium
pentode
► **pentosan**
pentose
pentose phosphate pathway
Pentothal
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pentstemon
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Narrower Terms:

[arabinose](#)

Narrower Terms:

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Scope Note:

monosaccharide containing five carbon atoms in a molecule.

Term Number:

2235-6128

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pentosan

See for:[*glycan*](#)**Broader Terms:**[polysaccharide](#)**Scope Note:****anhydride or polymerized form of any pentose.****Term Number:****2234-8636**

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Any of a group of sugars of the formula C₅H₁₀O₅, such as as arabinose or ribose; -- so called from the five carbon atoms in the molecule. They are not fermented by yeast. [Webster 1913 Suppl.]**pentose - WordNet (r) 2.0 (August 2003) :**

pentose

n : any monosaccharide sugar containing five atoms of carbon per molecule

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(Chem.)

One of a class of substances (complex carbohydrates widely
distributed in plants, as in fruits, gums, woods, hay, etc.)
which yield pentoses on hydrolysis.
[Webster 1913 Suppl.]

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